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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/824,767

04/15/2004

Gordon S. Sacks

WARF:004US

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7590 09/26/2007  
FULBRIGHT & JAWORSKI L.L.P.  
A REGISTERED LIMITED LIABILITY PARTNERSHIP  
SUITE 2400  
600 CONGRESS AVENUE  
AUSTIN, TX 78701-3271

EXAMINER

BLAND, LAYLA D

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

09/26/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/824,767	Applicant(s) SACKS ET AL.	
	Examiner Layla Bland	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 13-15, 20, 24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 13-15, 20, 24 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

***Detailed Action***

This office action is a response to applicant's amendment submitted August 13, 2007, wherein claims 1, 2, 13, 15, 24, and 25 are amended and claims 4-12, 16-19, and 21-23 are cancelled. This application is a continuation of U.S. Provisional Application 60/463,561, filed April 17, 2003. Claims 1-3, 13-15, 24, and 25 are pending and are examined on the merits herein.

Applicant's declarations of Gordon Sacks (inventor) submitted August 13, 2007 under 37 CFR 1.132, are acknowledged and will be further discussed below.

In view of the cancellation of claims 4-12, 16-19, and 21-23, all rejections made with respect to those claims in the previous office action are withdrawn.

Applicant's amendment submitted August 13, 2007, with respect to the rejection of claims 1, 3, 13-15, 24, and 25 under 35 USC 102 as anticipated by Shinal et al. has been fully considered and found to be persuasive to remove the rejection as the claims are now drawn to a formulation comprising a popsicle comprising pudding and water, wherein the unit dose is about 20 to about 40 grams L-glutamine. Therefore the rejection is withdrawn.

Applicant's amendment submitted August 13, 2007, with respect to the rejection of claims 1 and 2 under 35 USC 102 as anticipated by Sheratt et al. has been fully considered and found to be persuasive to remove the rejection as the claims are now

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drawn to a formulation comprising a popsicle comprising pudding and water. Therefore the rejection is withdrawn.

The following new rejections are based on applicant's amendments, wherein limitations regarding the unit dose and pudding popsicle medium are incorporated into claims 1, 13, 15, and 24.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 13-15, 20, 24, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shinal, et al. (WO/2000/069470, November 23, 2000, of record) in view of Sherratt, et al. (US 6,479,068 B1, November 12, 2002, of record).

Shinal, et al. teach a glutamine composition in the form of ice cream or frozen confections such as the common popsicle [page 13, lines 13-14]. Shinal, et al. also teach glutamine compositions for the treatment of oral lesions following radiation or chemotherapy [page 4, lines 5-12] and teaches that frozen formulations can be especially effective for the treatment of oral and esophageal ulcers, since they can

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combine the beneficial effects of glutamine with the soothing effects of the cold mixture [page 13, lines 12-17].

Shinal, et al. does not teach a glutamine composition in the form of pudding and does not teach a dosage of about 20 grams to about 40 grams.

Sherratt, et al. teach an oral composition comprising L-glutamine [abstract] that can be mixed into moist food such as pudding [column 9, lines 16-17], which contains water and flavoring. Sherratt, et al. also teach an effective daily dose of glutamine to be about 30 grams [column 4, lines 54-57].

One of ordinary skill in the art would be motivated to combine the frozen medium of Shinal, et al. with the dosage and pudding medium of Sherratt, et al. for the treatment of oral inflammation caused by chemotherapy or radiation in order to get the added benefit of the cold formulation with the appropriate dosage. One of ordinary skill in the art would be motivated to combine the popsicle of Shinal, et al. with the pudding of Sherratt, et al. in order to gain the added benefit of the cold composition with the taste of pudding, which some patients might prefer.

Furthermore, one of ordinary skill in the art would have been motivated to prepare a kit comprising L-glutamine, pudding mix, and a mold, and further comprising a sterile aqueous solution, anesthetic, or handle, for the reasons listed above and because the components of the kit are well-known to one of ordinary skill in the art.

***Response to Amendment***

Applicant's arguments filed August 13, 2007 have been fully considered but they are not persuasive. With respect to the rejection of claims 11, 18 and 23 under 35 USC 103, applicant argues that one of ordinary skill in the art would not turn to Sherratt et al. for a teaching of glutamine in puddings because Sherratt et al. deals with formulations to increase the uptake of glutamine, and it appears to be applicant's position that an increased uptake of glutamine leads to decreased delivery of glutamine to a subject. This is not found persuasive for two reasons: first, because Sherratt et al. teach the use of the glutamine pudding composition for the treatment of mucositis and stomatitis, which is the same use described in the instant specification; and second, because the examiner does not agree that increased uptake of glutamine decreases the amount of glutamine that is delivered to a subject. To the contrary, Sherratt et al. teach that increased and effective intracellular glutamine concentrations can be delivered to the gastrointestinal system without increasing the absolute glutamine dosage [page 25, lines 2-6].

The declaration under 37 CFR 1.132 filed August 13, 2007 is insufficient to overcome the rejection of claims 11, 18 and 23 based upon obviousness under 35 USC 103 as set forth in the last Office action because: the declaration of Gordon Sacks is insufficient to establish the fact that the claimed frozen pudding compositions exhibit surprising and unexpected benefits. The declaration presents a comparison of L-glutamine popsicles in a water medium versus a pudding medium. In the water medium, L-glutamine was found in a clump at the tip of the popsicle (bottom of the

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mold) and was not evenly suspended. In the pudding medium, L-glutamine was evenly suspended and no clumps were found. Pudding has a much thicker consistency than water; thus it is not surprising or unexpected that L-glutamine remained evenly suspended in the pudding mixture and not in the water mixture. Therefore, there is no clear and convincing evidence in the declaration for unexpected results. Therefore, the declaration is insufficient to rebut the prima facie case herein.

It is noted that, while claims 11, 18 and 23 have been cancelled, the discussions above are relevant to claims 1-3, 13-15, 20, 24, and 25 as amended.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Bland whose telephone number is (571) 272-9572. The examiner can normally be reached on M-R 8:00AM-5:00PM UST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Layla Bland  
Patent Examiner  
Art Unit 1623  
September 4, 2007

Shaojia Anna Jiang

  
Supervisory Patent Examiner  
Art Unit 1623  
September 4, 2007